

I. General Information:

K961943

- A. Generic (USAN) Name: hefilcon A
- B. Device Trade Name: FLEXILENS (hefilcon A) HARRISON Post Refractive Surgery Lens for Daily Wear
- C. Sponsor's Name and Address: FLEXILENS LLC
3241 South Zuni Street
Englewood, CO 80110
(800) 223-3539
- D. 510(k) Number: K961943

OCT 1 1996

II. Indications

The FLEXILENS (hefilcon A) HARRISON Post Refractive Surgery Contact Lens is indicated for Daily Wear use for the correction of refractive ametropia and specialized use such as atypical ametropia following corneal refractive surgery.

III. Device Description

The FLEXILENS (hefilcon A) Harrison Post Refractive Surgery Contact Lens for daily wear is a soft (hydrophilic) contact lens with a spherical or toric base curve and a spherical front surface. The lens is lathe cut from hefilcon A, a hydrophilic random copolymer of 2-hydroxyethyl methacrylate and N-vinyl pyrrolidone crosslinked with ethylene glycol dimethacrylate. It consists of 55% hefilcon A and 45% water by weight when immersed in normal saline solution buffered with sodium bicarbonate.

The physical properties of the lens are as follows:

- * Refractive Index: 1.43
- * Light Transmittance: greater than 95%T
- * Water Content: 45%
- * Oxygen Permeability: $Dk=16 \times 10^{-11}$ at 35 °C
(measured by the standard Fatt method)
- * Specific Gravity: 0.979 g/cc

The FLEXILENS (hefilcon A) Harrison Post Refractive Surgery Contact Lens for daily wear was developed to improve the visual acuity of those patients who require improved vision after photorefractive keratectomy, radial keratotomy, and other corneal refractive procedures. Other factors taken into consideration were the following:

1. The topographical profile is such that it is difficult to achieve a satisfactory posterior lens surface to cornea alignment with rigid gas permeable contact lenses.

2. Conventional soft (hydrophilic) contact lens designs do not readily align with the visual axis of the PRS or RK eye or supply sufficient masking of the corneal astigmatism.
3. Conventional toric soft (hydrophilic) contact lenses are limited in their ability to provide a stable level of visual acuity on cases of extreme central flattening in conjunction with irregular astigmatism.

The Harrison Post Refractive Surgery Lens differs from the standard spherical FLEXLENS Custom Sphere in that it incorporates a flat central optical zone with a thickness which varies with power (-1.00D will be approximately 0.30mm thick at the center). The size of the optical zone is generally 8.0mm. The peripheral carrier is thinner than most standard soft (hydrophilic) contact lenses, approximately 0.08 mm to 0.10 mm, to ensure limbal draping which will exhibit the characteristics (on the eye) of a peripheral aspheric design. In some cases the periphery is manufactured with a steeper curvature than the base curve.

IV. Alternative Practices or Procedures

Alternative practices or procedures are in the use of available prescription products: soft (hydrophilic) contact lenses or rigid gas permeable contact lenses or spectacles.

V. Technical Summaries

A. Pre Clinical

1. Toxicology

This was run on hefilcon A for the original N17-976 approved by FDA 01/04/79

2. Microbiology

This was run on hefilcon A for the original N17-976 approved by the FDA 01/04/1979

3. Compatibility

This was run on hefilcon A for the original N17-976 approved by the FDA 01/04/1979

4. Stability

This was run on hefilcon A for the original N17-976 approved by the FDA 01/04/1979. Presently we are have the shelf life at 4 years.

5. Preservative Uptake Tests

B. Clinical

The Sponsor is referencing a small clinical study that was run in Canada. There were 10 patients with 12 eyes. Average daily wear was 12.4 hours. The principal investigator was Keith W. Harrison, FCLSA. The lens was fitted to 6 patients following Photorefractive Keratectomy (PRK), 3 patients following a Radial Keratotomy (RK) and one patient following a corneal keratoplasty (also aphakic).

FLEXLENS, LLC last FDA inspection was completed on March 7, 1996.

- C. Potential Safety and Effectiveness as well as Adverse Effects of the Device on Health would be about the same as that of any other hefilcon A lens.

D. Conclusion drawn from Study

The safety and effectiveness lens should be equivalent to any other FLEXLENS (hefilcon A) lens.

- E. Since the geometry of the FLEXLENS (hefilcon A) HARRISON POST REFRACTIVE SURGERY lenses for Daily Wear is not much different from that of the standard Flexlens products a favorable recommendation from the FDA is anticipated. Should any additional information be required, it will be supplied by the individual whose name and address is on the cover letter of this 510(k) Notification.